

JUL 1 0 2000

K994409

**Alfa Scientific Designs, Inc.**

11494 Sorrento Valley Road, Suite M  
San Diego, CA 92121

## 510(K) Summary

In accordance with the Safe Medical Devices Act of 1990, a 510(K) summary is provided as outlined in 21 CFR 807.92.

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### Submitter

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San Diego, CA 92121

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### Device Name

**Trade Name:** *Instant-View™ Morphine Urine Dip Strip Test*

**Common Name:** Opiate Test

**Classification Name:** 21 CFR 862.3650, Class II

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### Predicate Device

The *Instant-View™ Morphine Urine Dip Strip Test* is substantially equivalent to other legally marketed devices for the similar intended use. The device used for comparison study is *QuikStrip One Step Opiate Test*, manufactured by *Syntron Bioresearch, Inc.* with 510(K) #: K972571, Date of Approval: 08/20/97.

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### Device Description

This test is a one-step lateral flow chromatographic immunoassay.

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### Intended Use

The *Instant-View™ Morphine Urine Dip Strip Test* is a qualitative immunoassay device intended to detect morphine only in human urine at a cutoff level of 300 ng/ml. It is for health care professional use only.

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### Summary of the Similarities to the Predicate Device

- Intended Use:  
Both devices are intended to detect morphine in human urine at a cutoff level of 300 ng/ml.
- Interpretation of results:  
The appearance of only a C line indicates a positive result, and that the morphine level is at a cutoff level of 300 ng/ml or higher. And, the appearance of two lines – both C line and T line indicates a negative result, and the

morphine level is below 300 ng/ml.

- **Technological Characteristics:**  
Both devices are one step, qualitative, competitive binding immunoassay test, utilizing the basic immunochemical sandwich assay principle of recognition and formation of the specific Morphine/Antibody/Morphine complexes.

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**Discussion and  
Conclusion**

- The correlation of results from the *Instant-View™ Morphine Urine Dip Strip Test*, and the legally marketed test device compared, is higher than 91.3 %. The results from all three POL sites agreed 92.5%.
- The Accuracy evaluation results from the Clinical Laboratory and three Physician's Offices conducted by persons with diverse educational background and working experience agreed 96.2 % with the expected results.
- Based on the results of the Performance Characteristics and Comparison Studies, it may be concluded that the *Instant-View™ Morphine Urine Dip Strip Test* is suitable for use by health care professionals with diverse educational backgrounds and work experiences, and is substantially equivalent to the existing legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 1 0 2000

Ms. Rhoda Filipina  
QA Manager  
Alfa Scientific Designs, Inc.  
11494 Sorrento Valley Road  
Suite M  
San Diego, California 92121

Re: K994409  
Trade Name: Instant-View Morphine Urine Dip Strip Test  
Regulatory Class: II  
Product Code: DPK  
Dated: June 6, 2000  
Received: June 8, 2000

Dear Ms. Filipina:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

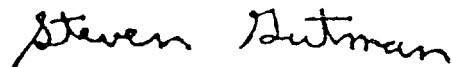
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

1K994409

510(k) Number (if known): K994409

Device Name: Instant-View Morphine Urine Dip Strip Test

Indications For Use:

**Instant-View Morphine Urine Dip Strip Test is a qualitative one step lateral flow, competitive binding immunoassay device intended to be used to detect morphine only in human urine at a cutoff level of 300 ng/ml. It is intended for health care professional use only.**

**The US Substance Abuse and Mental Health Services Administration (SAMHSA) recommends the screening levels for Morphine to be at a concentration of 2000 ng/ml.**

**This Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse, particularly when preliminary positive results are used.**

[Signature]  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 994409

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)